PROTOCOL #_____
Date of last renewal _____
IRB Office Use Only

MARYLAND DEPARTMENT OF HEALTH AND MENTAL HYGIENE
OFFICE OF THE INSPECTOR GENERAL
INSTITUTIONAL REVIEW BOARD

CONTINUING REVIEW
FORM II (DHMH 2125)

DHMH PROTOCOL #_____

TITLE OF STUDY: _____
_____
_____

PRINCIPAL INVESTIGATOR: _____ _____
SIGNATURE **PRINT OR TYPE NAME**

CO-PRINCIPAL INVESTIGATOR: _____ _____
SIGNATURE **PRINT OR TYPE NAME**

STUDENT INVESTIGATOR: _____ _____
(Academic Advisor should be PI) **SIGNATURE** **PRINT OR TYPE NAME**

MAILING ADDRESS: _____
(only if it has changed since _____
the last renewal) _____
_____

PHONE # _____FAX #_____E-MAIL_____

NAME OF DHMH PROGRAM ADMINISTRATOR(S) AUTHORIZING CONTINUOUS INVOLVMENT IN THIS STUDY: **(Obtain signature(s) prior to submission to the IRB for review. Will not be reviewed without signature(s))**

1._____ SIGNATURE_____
(PRINT)

2._____ SIGNATURE_____
(PRINT)

3._____ SIGNATURE_____
(PRINT)

4._____ SIGNATURE_____
(PRINT)

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PROJECT STATUS:

A.

____ Study complete and:
(check all that apply)

____ Inactive (no further contact with human subjects or data)

____ Original data and/or research material have been destroyed

____ The linkage between the existing data and original source of information has been destroyed

____ Data with identifiers will be retained (indicate in a separate memorandum why such data will be retained, where and how long). **This requires an annual report on confidentiality measures**

____ Project never initiated

B.

___ Study is active and:
(check all that apply)

____ Currently enrolling subjects

____ Subject enrollment complete

____ Subjects in follow up phase(s)

____ Data still being collected from records (study involves data abstraction only)

____ Data still being collected from DHMH agency (e.g. MCR, VSA, or Medicaid)

____ Data analysis only (all data collected or patients enrolled, all follow-up completed)

C. Has there been any change in the procedures for protecting human subjects? ____Yes ____No (If yes, please explain in a separate memorandum and attach)

D. Have there been any changes in the consent process (if applicable) ____Yes ____No

E. Has there been any evidence either from your experience to date or from recent literature which indicate the existence of risks different from those previously described? ___Yes ___No (If yes, briefly describe in a separate memorandum and attach.)

F. What is the total number of subjects you expect to recruit for this study? _____ (If this study does not involve subject recruitment (but data collection only) indicate with N/A)

G. Number of subjects accrued this year? _____ (____men ____women)
Since the study began? _____ (____men ____women)

H. Has there been a withdrawal of any subjects from the research since your last review? ___Yes ___No (If yes, briefly describe in a separate memorandum and attach.)

I. Have there been any complaints about the research? ___Yes ___No
(If yes, briefly describe in a separate memorandum and attach.)

J. Have there been any SAEs (Serious Adverse Events)? ___Yes ___No (If yes, briefly describe in a separate memorandum and attach.)

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K. If your study involves the collection of death certificates only provide the following information:

- Total number of death certificates received (from Maryland) this year_____
- Total number of death certificates received (from Maryland) since the study begin _____

L. Has this study been modified since the last review? ___Yes ___No
If yes, was the modification (s) approved ___Yes ___No
List all modifications and indicate approval date for each (if more space is needed use a separate sheet of paper)

_____
_____
_____
_____
_____
_____

M. Are you requesting a modification with this review? ___Yes ___No (If yes, provide a complete description of the modification along with details regarding the need for the changes and indicate if the changes will affect the risk level of the study)

N. Have you published any articles resulting from this study? ___Yes ___No
If yes, have you provided copies to the Administration providing the data as well as to the IRB?
___Yes ___No

**********************DO NOT WRITE BELOW THIS LINE – IRB USE ONLY**********************

___Protocol is as previously approved research may continue (if applicable, VSA agreement remains in effect)

___Protocol is approved as modified

___Protocol is as previously approved but risks have increased based on current knowledge, IRB full review completed and protocol approved

___Protocol is not adhering to proposal as approved, research must cease

___Study remains active for data analysis only

___Study never initiated

___Study complete, but data with identifiers will be retained and PI will continue to assure confidentiality and advise the IRB of any breech of confidentiality via annual report

___Study complete – data linkage destroyed

___Study has been modified and no longer qualifies as research, exempt from any further IRB review

___Study has been modified and qualifies as exempt research according to 45CFR46 101(b) _____

Signature_____ Date_____
Chairperson, DHMH Institutional Review Board